

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2123689	<b>(X3) Date Survey Completed</b>  08/30/2018
<b>Name of Provider or Supplier</b>  Midstate Skin Institute Llc	<b>Street Address, City, State</b>  3210 Sw 33rd Road Ste 101, Ocala, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was conducted on August 30, 2018. Midstate Skin Institute LLC clinical laboratory had one deficiency found at the time of the visit.
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review, and interview, it was determined that the laboratory did not monitor the Cryostat ( Avantik QS 12 ) temperature requirements to assure optimal operation temperatures several days from April to October 2017. Review of the laboratory procedures indicated that the Cryostat ( Avantik QS 12 ) operates at a freezing temperature of -21 degrees to -30 degrees Celsius. The temperature log for the year 2017 ( 4/27, 5/4, 6/1, 6/14, 7/24, 9/7, and 10/19 ) showed abnormal ranges of -14 to -20 degrees Celsius. There was no corrective action available for documenting the temperature of the Cryostat which showed out of range temperatures. Interview on 8/30/18 at 11:00 AM, testing person # 3 confirmed that the temperature of the Cryostat which showed out of range for 2017 was not reported to the supervisor and no corrective actions were documented.</p>